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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,066	01/24/2005	Stanley George Bonney	PG4884USw	7458

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GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B482

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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3772

NOTIFICATION DATE

DELIVERY MODE

06/27/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/523,066

Applicant(s)

BONNEY ET AL.

Examiner

NIHIR PATEL

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03.26.2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-13 and 15-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on March 26th, 2008 have been fully considered but they are not persuasive. The applicant argues that there is no suggestion in Riccio that cylinder 18 be used as a first medicament container containing a first medicament as recited in claim 1. The examiner disagrees with the applicant's argument. Column 5 lines 25-30 of the Riccio reference states that "Moreover, while the piston cylinder air pressurizing means have been described as a specific source of gas under pressure, other sources could be provided, for example, a valved conventional aerosol can containing a conventional propellant under pressure." This statement provides an implicit teaching that the cylinder 18 can be used as a first medicament container as recited in claim 1.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1-4, 12-14, 17 and 18** are rejected under 35 U.S.C. 102(b) as being anticipated by Riccio (US 3,923,202).

4. **As to claims 1, 17 and 18**, Riccio teaches an apparatus that comprises a first medicament container **18** containing the first medicament (**see figure 1**); at least one further medicament dispenser **32** containing the at least one further medicament (**see figure 1**); a mixing chamber **17**

(see **figure 1**) comprising inlets for receiving medicament from each medicament dispenser and an outlet for delivery of the combination medicament dispenser (see **column 5 lines 1-10**); wherein said first medicament dispenser and said at least one further medicament dispenser enable the first and the at least one further medicament to be kept separate until the point of device, and the first medicament dispenser is different in type to the at least one further medicament dispenser (see **column 4 lines 55-68 and column 5 lines 1-10**).

5. **As to claim 2**, Riccio teaches an apparatus wherein the device comprises the first medicament dispenser and only one further medicament dispenser (see **figure 1**).

6. **As to claim 3**, Riccio teaches an apparatus wherein the first medicament dispenser is selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi-dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI) and the at least one further medicament dispenser is selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi-dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI) (see **column 4 lines 55-68**).

7. **As to claim 4**, Riccio teaches an apparatus wherein the first medicament dispenser is a reservoir dry powder inhaler (RDPI), and the at least one further medicament dispenser is of a type selected from the group consisting of a multi-dose dry powder inhaler (MDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI) (see **column 4 lines 55-68**).

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8. **As to claim 12**, Riccio teaches an apparatus wherein the metered dose inhaler (MDI) is arranged to reversibly receive a liquid container suitable for containing medicament in liquid form (see column 4 lines 55-68).
9. **As to claim 13**, Riccio teaches an apparatus that comprises a coupled actuator for the first medicament dispenser and the at least one further medicament dispenser (see figure 1).
10. **As to claim 14**, Riccio teaches an apparatus wherein said outlet communicates with a common mouthpiece 14 (see figure 1).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Riccio (US 3,923,202).

14. **As to claim 23**, Riccio substantially discloses the apparatus for performing a method see rejection above. Further, Riccio also discloses the method step of providing a patient in need thereof a medicament dispenser device and dispensing a combination medicament product from said device (see column 4 lines 55-68 and column 5 lines 1-10).

15. Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riccio (US 3,923,202) in view of Marand (US 3,704,725).

Riccio does not teach a unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product.

However, Marand teaches a unitary medicament dispenser (**Figure 1**), product container (**first medicament dispenser**), (**1**) and a propellant: cartridge (**at least one further medicament dispenser**) (**9**), that dispenses a combination medicament product by means of coupler-aspirator (**3**). Therefore, it would have been obvious, to one having ordinary skill in the art at the time of the invention, to modify the device of Riccio to allow the dispensing of a combination medicament product, as taught by Marand, as such a modification would allow a user or patient to inhale a specialized medicament for an appropriate treatment that results from two separate initial medicaments.

16. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riccio (US 3,923,202) in view of Makiej, Jr. (US 5,002,048).

17. **As to claims 19-22**, Riccio substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a first medicament that comprises a bronchodilator (beta-

agonist) and the at least one further medicament comprises an anti-inflammatory (steroid). Makiej teaches an apparatus that does provide a first medicament that comprises a bronchodilator (beta-agonist) and the at least one further medicament comprises an anti-inflammatory (steroid) (see **column 3 lines 1-15**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Riccio's invention by providing a first medicament that comprises a bronchodilator (beta-agonist) and the at least one further medicament comprises an anti-inflammatory (steroid) as taught by Makiej in order to make it easier to breathe.

18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Riccio (US 3,923,202) in view of Anderson et al. (US 6,958,691).

19. **As to claim 16**, Riccio substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a breath sensor for sensing the breath of a patient wherein actuation of the first medicament dispenser and/or the at least one further medicament dispenser is responsive to said breath sensor. Anderson teaches an apparatus that comprises a breath sensor for sensing the breath of a patient wherein actuation of the first medicament dispenser and/or the at least one further medicament dispenser is responsive to said breath sensor (see **column 11 lines 5-15**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Riccio's invention by providing a breath sensor for sensing the breath of a patient wherein actuation of the first medicament dispenser and/or the at

least one further medicament dispenser is responsive to said breath sensor as taught by Anderson in order to prevent waste of medicament.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772